

Translation

# PATENT COOPERATION TREATY PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>YCT-918</b>	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. <b>PCT/JP2004/003873</b>	International filing date ( <i>day/month/year</i> ) <b>22.03.2004</b>	Priority date ( <i>day/month/year</i> ) <b>20.03.2003</b>

International Patent Classification (IPC) or national classification and IPC

Applicant

**CHUGAI SEIYAKU KABUSHIKI KAISHA**

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of **6** sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a.  (*sent to the applicant and to the International Bureau*) a total of \_\_\_\_\_ sheets, as follows:

sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b.  (*sent to the International Bureau only*) a total of (indicate type and number of electronic carrier(s))

, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

<input checked="" type="checkbox"/>	Box No. I Basis of the report
<input type="checkbox"/>	Box No. II Priority
<input type="checkbox"/>	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI Certain documents cited
<input checked="" type="checkbox"/>	Box No. VII Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT / JP2004/003873

## Box No. I

## Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- international search (Rule 12.3 and 23.1(b))
- publication of the international application (Rule 12.4)
- international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished  
 the description:

pages \_\_\_\_\_ as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the claims:

nos. \_\_\_\_\_ as originally filed/furnished

nos.\* \_\_\_\_\_ as amended (together with any statement) under Article 19

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

nos.\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

the drawings:

sheets \_\_\_\_\_ as originally filed/furnished

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

sheets\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/JP2004/003873

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Claims <u>1-18</u>	YES
	Claims _____	NO
Inventive step (IS)	Claims _____	YES
	Claims <u>1-18</u>	NO
Industrial applicability (IA)	Claims <u>1-18</u>	YES
	Claims _____	NO

**2. Citations and explanations (Rule 70.7)**

Document 1: Wayner et al., "Quantitative measurement of the total, peroxy radical-trapping antioxidant capability of human blood plasma by controlled peroxidation", FEBS Letters, vol. 187, no. 1 (1985), pages 33 to 37

Document 2: Kritharides et al., "A method for defining the stages of LDL oxidation", Analytical Biochemistry, vol. 213 (1993), pages 79 to 89

Claims 1 to 18

Document 1 cited in the international search report sets forth a method of assessing the antioxidant function in a blood sample, wherein a blood sample is taken from the body, an oxidation reaction is commenced, the oxidation reaction is continued, and the antioxidant component is assessed from the progress of said oxidation reaction.

Document 2 cited in the international search report indicates that in order to investigate the oxidation reaction of LDL contained in a blood constituents, LDL is

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**Box No. V** **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

subjected to an oxidation reaction, and cholesterol oxides and cholesterol peroxides, the product of said reaction, are measured.

Here, the invention set forth in document 2 measures the oxidation reaction of blood constituents, therefore when investigating the progress of the oxidation reaction set forth in document 1, it would be obvious to a person skilled in the art to apply the invention set forth in document 2, to constitute a configuration similar to that set forth in the claims of this application.

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International application No.

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**Box No. VII      Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

In the light of the description, only when the antioxidant component is alpha-tocopherol in the blood, the oxidized substance is fat in the blood, and the oxidation products from fat are cholesterol ester hydroxide and cholesterol ester hydroperoxide, is the effect obtained that a risk assessment can be made of the lesions which are aggravated by oxidation stress by measuring the oxidation reaction which progresses in the presence of antioxidant components within the body. However, this feature is not clearly disclosed in the claims of this application.

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**Box No. VIII      Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 15 and 16 pertain to the relationship between different disorders and the antioxidant capability of a biological sample, but the correlation between the two is not supported by a technically appropriate explanation in the description of this application.